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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,312	03/17/2004	R. Peter Santarpia III	6857-01	1962

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EXAMINER
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ROBERTS, LEZAH

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/801,312	<b>Applicant(s)</b> SANTARPIA ET AL.	
	<b>Examiner</b> Lezah W. Roberts	<b>Art Unit</b> 1614	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### *Claims*

#### **Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "Carbomer" in claims 1-14 is used by the claim to mean "a carboxymethylene polymers, acrylic acid polymers, acrylic acid and copolymers" (see instant specification at page 4), but its accepted meaning is as a trade name for polymers of acrylic acid, cross-linked with allyl sucrose. The term is indefinite because the specification does not clearly redefine the term.

**Claim Rejections - 35 USC § 102 – Anticipation**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-7, 11, 13 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Cleary (US 2003/0027833).

Cleary et al. teaches pharmaceutical compositions comprising a local anesthetic agent; and a pharmaceutically acceptable carrier comprised of a monohydric alcohol, a penetration enhancer, and a polymer, which may be a hydrophilic polymer, a hydrophobic polymer or a combination thereof. The composition may form a gel or a film is formed following application to a patient's body surface and evaporation of the monohydric alcohol (see abstract). The amount of monohydric alcohol present in the carrier determines whether a film or gel is formed, e.g., when in the range of about 40 wt. % to about 90 wt. % based on the total weight of the composition, the composition forms a film following application to a body surface and concomitant and/or subsequent evaporation of the alcohol. When a relatively smaller quantity of the monohydric alcohol

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is incorporated into the composition, e.g., less than about 40 wt. %, the composition forms a gel (page 2, paragraph 0022). Preferable alcohols include ethanol and isopropanol (page 5, paragraph 0062). The range of the vehicle is dependent on the consistency of the composition. The penetration enhancer incorporated in the composition of the enclosed invention include polyethylene glycol (polyethylene oxide), propylene glycol, as well as other enhancers and combinations thereof in a concentration ranging from about 0.1 to 20 wt. percent of the composition (page 6, paragraphs 0065-0066). When in combination, one of the enhancers can act as a humectant, as recited in claim 8 with a weight percent corresponding to what is recited in claim 9. Hydrophilic polymers used in the compositions include Carbopol®, polymers generally formed from acrylic acid, methacrylic acid, methyl acrylate, ethyl acrylate, methyl methacrylate, ethyl methacrylate, and/or other vinyl monomers. Preferred acrylate polymers are copolymers of methacrylic acid and methyl methacrylate (page 6, paragraph 0070). Water may also be present in the compositions (page 7, paragraph 0076). In addition to the anesthetics used in the compositions, other active agents may be included, one of which is hydrogen peroxide (page 4, paragraph 0051) and may be included from 0.1 to 50 weight % of the composition (page 5, paragraph 0058). The pH regulators that may be used in the compositions include citrate and phosphate buffers (page 8, paragraph 0086). The compositions are used for several purposes one of which is to treat oral pain in the mouth (page 9, paragraph 0100). Administration of the active agent can be carried out once, twice, three times or four times daily. Alternatively, or in addition to regularly scheduled doses, administration may be carried

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out on an "as needed" basis, or using a drug delivery system adapted to provide sustained drug delivery over an extended time period (page 10, paragraph 0105). The combination of the polyethylene oxide and the CARBOPOL result in the formation of the gel or film and the amounts disclosed by the reference encompass those disclosed by the instant claims. The reference anticipates the instant claims insofar as to disclose a composition comprising of peroxide, a monohydric alcohol, and a film forming combination of a polyethylene oxide and a Carbomer. The prior art compositions appear to be substantially the same as Applicant's; accordingly, Applicant's recitation of intended use has been given no weight. The prior art compositions will be useful for the same purposes claimed by Applicant whether explicitly recognized or not.

### **Claim Rejections - 35 USC § 103- Obviousness**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen et al. (US 6,306,370) in view of Cleary (US 2003/0027833).

Jensen et al. teach dental whitening compositions containing bleaching agents and tackifying agents. The bleaching agents that are utilized in this invention are hydrogen peroxide and carbamide peroxide, also called urea peroxide (col. 1, lines 45-48), and make up about 0.5 to about 50% by weight of the disclosed compositions, as recited in claims 6 and 7. The tackifying agents that are used are carboxypolymethylene, and in addition to this, POLYOXN and a mixture of polyethylene oxides having a molecular weight of 100,000-8,000,000 may also be utilized, as recited in claim 2. The concentration of carboxypolymethylene ranges from 0.5 to 25% by weight of the dental whitening composition, as recited in claims 4 and 5. Compositions can be made to the desired tackiness determined by how the composition is applied to the teeth (col. 7, lines 30-47). In the examples disclosed by the patentee, the compositions contain a mixture of the above polymers in which polyethylene glycol is used at 5.5 percent as recited in claim 3. Polyethylene glycol is also a humectant therefore encompassing claims 8 and 9. The carrier system comprises water in an amount of 0 to about 50% by weight and glycerin ranging from about 15 to about 85% by weight, as recited in claim 10. Glycerin may be substituted with other polyhydric alcohols and other alcohols (col. 8, lines 15-59), which encompasses claim 11. The pH of the solutions ranges from 4-9, preferably 5-7 (col. 8, lines 65-67 and col. 9, lines 1-2), as recited in claim 12. The compositions may be applied directly to the teeth using a

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brush tip applicator (col. 11, lines 39-41). Exposure times vary and involve repeated exposures over several days (col. 13, lines 34-44), as recited in claim 14. The reference differs from the instant claims insofar as to not disclose the specific use of a monohydric alcohol as an alcohol that can be used within the compositions.

The secondary reference is as stated above. The reference differs from the instant claims insofar as to not disclose the compositions as teeth whitening compositions.

It would have been obvious to one of ordinary skill in the art to have used the monohydric alcohol of the secondary reference as an alcohol used in the primary reference, motivated by the desire to promote faster film or gel formation on the teeth by using an alcohol that evaporates quickly once the composition is applied to the teeth as stated by the secondary reference.

It would also have been obvious to one of ordinary skill in the art to have used a buffering salt of the secondary reference to maintain the pH of the composition because buffers are made to be a particular pH and would therefore be added in a certain amount as opposed to a base which would be titrated in to the desired pH.

### **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct



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from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,770,266.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite a tooth whitening liquid containing a peroxide (hydrogen or urea), water, monohydric alcohol and combination of poly(ethylene oxide) and Carbomer. The compositions have a pH ranging from 3.5-5.5 where a buffering agent stabilizes the pH. The weight percents recited by the claims of the patent and the instant claims correspond to one another and the method claims are similar.

Claims 1-14 are rejected.

No claims allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Patent Examiner  
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Frederick Krass  
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